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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
GAMBEL, PHILLIP	
ART UNIT	PAPER NUMBER
1644	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/501,102	CO ET AL.	
	Examiner	Art Unit	
	Phillip Gambel	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 April 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *145,147,149-153 and 161-164* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *145, 147, 149-153, 161-164* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment, filed on 04/16/2009, has been entered.

Claims 145, 147, 149 and 152 have been amended.

Claims 161-164 have been added.

Claim 154 has been canceled.
Claims 1-144, 146, 148 and 155-160 have been canceled previously.

Claims 145, 147, 149-153 and 161-164 are pending.

Again for the record and as indicated previously, claims 145, 147 and 149-154, as they read on the elected invention, including the elected species of the combination of anti-B7-1 antibodies, anti-B7-2 antibodies and cyclosporin or rapamycin in the claimed methods are under consideration in the instant application.

Also, as noted previously, the previously amended recitation of administering an additional (third) agent, is read on administering cyclosporin or rapamycin as the additional (third) agent only.

Accordingly, the third agents other than cyclosporin or rapamycin are withdrawn from consideration as being directed to a non-elected invention. See 37 C.F.R. 2(b) and M.P.E.P. 821.03.

2. The text of those sections of Title 35 USC not included in this Action can be found in a prior Office Action.

This Action will be in response to applicant's arguments, filed 04/16/2009.

3. Priority.

Upon reconsideration of the recitation of applicant's amended and newly added claims, filed 04/16/2009, the effective filing date of the instant claims is deemed to be the filing date of the priority document USSN 09/249,011, filed 02/12/2009.

4. Upon reconsideration of applicant's amended claims, filed 04/16/2009; the previous rejection under 35 U.S.C. 112, second paragraph, with respect to the recitation of "modulating" has been withdrawn.

5. Claims 161-163 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) Claim 161 is indefinite in the recitation of "III2R heavy chain framework region" and the "H2F light chain framework region" because their characteristics are not known. The use of "III2R" and "H2F" as the sole means of identifying the claimed referenced antibodies or framework regions thereof renders the claim indefinite because "III2R" and "H2F" are merely laboratory designations which do not clearly define the claimed product, since different laboratories may use the same laboratory designations to define completely distinct antibodies or immunoglobulins.

Applicant is invited to amend the claims to provide either the proper sequences (e.g., see claims 162) or to provide the appropriate deposit information.

B) Claims 162-163 are indefinite in the recitation of "and wherein treatment of the autoimmune disease occurs" for lacking proper antecedent basis to the preamble of the claimed "methods to treat a transplant recipient of preventing transplant rejection in a transplant recipient".

Applicant is invited to amend the claims for proper antecedent basis.

C) Applicant is reminded that the amendment must point to a basis in the specification so as not to add any new matter. See MPEP 714.02 and 2163.06

6. Claim 161 is rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention

It is apparent that the III2R and H2F antibodies / immunoglobulins are required to practice the claimed invention. As required elements, they must be known and readily available to the public or obtainable by a repeatable method set forth in the specification. If it is not so obtainable or available, the enablement requirements of 35 USC 112, first paragraph, may be satisfied by a deposit of the appropriate cell lines / hybridomas which produces this antibody. See 37 CFR 1.801-1.809.

In addition to the conditions under the Budapest Treaty, applicant is required to satisfy that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent in U.S. patent applications. See MPEP 240.01 and 37 CFR 1.808.

Amendment of the specification to recite the date of deposit and the complete name and address of the depository is required. As an additional means for completing the record, applicant may submit a copy of the contract with the depository for deposit and maintenance of each deposit.

If the original deposit is made after the effective filing date of an application for patent, the applicant should promptly submit a verified statement from a person in a position to corroborate the fact, and should state, that the biological material which is deposited is a biological material specifically identified in the application as filed, except if the person is an attorney or agent registered to practice before the Office, in which the case the statement need not be verified. See MPEP 1.804(b).

Affidavits and declarations, such as those under 37 C.F.R. § 1.131 and 37 C.F.R. § 1.132, filed during prosecution of the parent application do not automatically become a part of this application. Where it is desired to rely on an earlier filed affidavit, the applicant should make the remarks of record in the later application and include a copy of the original affidavit filed in the parent application.

Given the disclosure and the claims encompassing the instant cA2 antibody set forth in U.S. Patent No. 6,984,383; the conditions for the deposit of biological materials under 35 USC § 112, first paragraph, with respect to III2R and H2F may have been satisfied.

However, applicant is required to make the record clear exactly what is the scope of the instantly claimed III2R and H2F antibodies / immunoglobulins and whether applicant has satisfied the deposit requirements under 35 USC 112, first paragraph, for the claimed III2R and H2F antibodies / immunoglobulins.

If applicant is relying upon sequence information to satisfy the deposit of biological materials, it is noted that the sequence of an entire immunoglobulin satisfies the biological deposit of said immunoglobulin. Note that satisfaction for the biological deposit of the specific III2R and H2F antibodies / immunoglobulins requires the disclosure and recitation of its entire amino acid sequence and not based upon partial sequences

7. Given the recitation of either the 1F1 antibody, III2R heavy chain framework region and/or H2F framework region;
the previous rejection under 35 U.S.C § 102(e) as being anticipated by Freeman et al. (U.S. Patent No. 6,605,279) has been withdrawn.

8. Given the recitation of either the 1F1 antibody, III2R heavy chain framework region and/or H2F framework region;
the previous rejection under 35 U.S.C § 102(f) has been withdrawn.

Applicant's arguments, including issues associated with the previous (12/14/2008) or currently submitted (04/16/2009) Gray Declaration under 37 CFR 1.132, have been rendered moot in view of the 1F1 antibody, III2R heavy chain framework region and/or H2F framework region

9. Given the recitation of either the 1F1 antibody, III2R heavy chain framework region and/or H2F framework region;
the previous rejection under 35 U.S.C § 102(b) as being anticipated by (WO 95/03408) Freeman et al. (U.S. Patent No. 6,605,279) has been withdrawn.

10. Given the recitation of either the 1F1 antibody, III2R heavy chain framework region and/or H2F framework region;
the previous rejection under 35 U.S.C § 103(a) as being unpatentable over Freeman et al. (U.S. Patent No. 6,605,279) OR Freeman et al. (WO 95/03408) in view of the well known use of immunosuppressives such as cyclosporin, FK506 and rapamycin and effective therapeutic antibody dosages in transplantation therapeutic regimens at the time the invention was made, as taught by de Boer et al. (U.S. Patent No. 5,757,034) has been withdrawn

11. Claims 145, 147, 149-153 and newly added claims 161-164 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable
over claims 1-61 of U.S. Patent No. 6,827,934 for the reasons of record,
over claims 1-18 of U.S. Patent No. 6,984,383 (1449; #AA) for the reasons of record and \
over claims 1-61 of U.S. Patent No. 7,531,175.

The patented claims drawn to methods of therapeutic regimens of transplantation with B7-specific antibodies either anticipate or render obvious the instant claims.

The claims of U.S. Patent No. 7,531,175 are similarly drawn to methods of inhibiting immune response in a transplantation regimen, including reliance upon the same or nearly the same 1F1 anti-B&-1 antibody as well as the same III2R framework regions as the instant claimed methods.

Also, as to the use of a combination of immunosuppressive therapy in transplantations therapeutic regimens or timing of administration of immunosuppressive agents during transplantation regimens,
methods of administration are a result effective variable and immunosuppressive therapy including rapamycin were routine at the time the invention was made by the ordinary artisan.

It is well settled that "discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art." In re Boesch, 617 F.2d 272, 276, 205 USPQ 215, 219 (CCPA 1980). See also Merck & Co. v. Biocraft Labs. Inc., 874 F.2d 804, 809, 10 USPQ2d 1843, 1847-48 (Fed. Cir. 1989) (determination of suitable dosage amounts in diuretic compositions considered a matter of routine experimentation and therefore obvious).

12. Claims 145, 147, 149-153 and newly added claims 161-164 are directed to an invention not patentably distinct from
from claims 1-61 of commonly assigned U.S. Patent No. 6,827,934;
from claims 1-18 of commonly assigned U.S. Patent No. 6,984,383 (1449; #AA) and
from claims 1-61 of commonly assigned U.S. Patent No. 7,531,175
for the reasons of record and above.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300). Commonly assigned U.S. Patent No., discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004

13. Given that the instant claims are drawn to methods of treating in terms of transplantation and that the pending claims of USSN 11/294,680 are drawn to methods of treating in terms of autoimmune diseases,
The previous provisional rejection under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the claims USSN 11/294,680 has been withdrawn.

14. No claim allowed.

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (571) 272-0844. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735.

The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Phillip Gambel/
Primary Examiner
Art Unit 1644
Technology Center 1600
July 6, 2009